Remarks

Reconsideration of this Application is respectfully requested.

Claims 1-18 are pending in the application, with claims 1, 8 and 15 being the independent claims. Claims 1 and 8 have been amended to correct minor grammatical errors therein. These changes are believed to introduce no new matter and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Amendment to the Specification

The Specification has been amended to include a priority claim under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application No. 60/442,126, filed January 24, 2003. This priority claim was included in an application data sheet that was filed along with the present application on January 26, 2004, and is therefore proper. *See* 37 C.F.R. § 1.78. This amendment adds no new matter and its entry is respectfully requested.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 1, 4-8, 11-15 and 18 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2002/0052761 A1 to Fey *et al.* ("Fey"). For the reasons set forth below, Applicants respectfully traverse.

Independent claim 1 is directed to an anonymous testing method that includes the steps of:

> providing a patient with an Alias ID and a Password;
>
> obtaining a test sample from the patient identified only by the Alias ID;
>
> testing the sample to obtain test results; and
>
> providing the test results to the patient using the Alias ID and Password.

The method of claim 1 protects the anonymity of a patient that is providing a sample, such as a DNA sample, for testing. In accordance with claim 1, the patient is provided with both an Alias ID and a Password prior to submitting the test sample. As set forth in the specification of the present application, "the Alias ID is a unique patient identifier that allows the patient to be identified without personal identifying information such as the patients name and address." *See* Specification at paragraph [0025]. The patient then collects the test sample and submits it, wherein the test sample is identified only by the Alias ID. After the test sample has been tested to obtain test results, the patient obtains the test results using both the Alias ID and the Password.

The invention of claim 1 solves the problem of protecting the patient's anonymity during the period where the test sample is being provided to and handled by a laboratory for testing. As set forth in the specification of the present application:

> Having both an Alias ID and Password allows the system to provide extra security and anonymity to patients. The DNA sample the patient supplies can be identified only by the Alias ID. Accordingly, when the patient sends their DNA sample to a laboratory for testing, the patient does not need to include the patient's Password, only the patients Alias ID. Accordingly, laboratory workers or other people who come in contact with the sample, such as physicians who may analyze the results, will not have both the Alias ID and the Password.

Specification at paragraph [0028]. Because the laboratory receives the test sample identified only by the Alias ID of the patient, "the laboratory personnel do not receive any information that could be used to identify the patient by name." Specification at paragraph [0043].

This method is distinguishable from prior art methods, such as those described in U.S. Patent Publication No. 2002/0137025 A1 to Quattrocchi ("Quattrocchi"), in which a patient sends a blood sample to a laboratory, wherein the blood sample is identified by a personal code that can later be used by the patient to obtain test results corresponding to the blood sample. As discussed in the Background Section of the present application:

> The method in Quattrochi is limited in that it fails to adequately secure the personal code. The patient's personal code is available to everyone who has access to the test kit and the patient's specimen. Accordingly, Quattrochi only offers the patient limited anonymity.

Specification at paragraph [0006].

Fey is directed to a genetic health data management system. In Fey, a DNA sample is collected from a consumer and is then sent to a Genetic/Health Screening Facility for storage and/or testing. *See* Fey at paragraph [0068]. In contrast to the method of claim 1, during the process of collecting the DNA sample from the consumer for storage and/or testing, the anonymity of the consumer is not protected by using an Alias ID or a Password. As described in Fey:

> In one embodiment, individual consumers order DNA testing kits from the health facility, either over the phone, in person or online. Upon receipt of the kit, the consumer follows the directions in the kit, swabbing inside their cheek with the sterile material provided, then returns the kit to the health facility. The individual's demographic data is entered into the database along with the time and date the DNA was received. If genetic screening tests were ordered at the same time, information is also entered about the tests

> or test package desired. ***The cost for any tests ordered is automatically calculated and the health facility professional notifies the consumer, if the consumer has not included the correct amount.***

Fey at paragraph [0069] (emphasis added). As can be seen from the foregoing text from Fey, an Alias ID is not provided to the consumer with the DNA testing kit and thus the anonymity of the consumer providing the DNA sample is not protected when submitting the sample. For example, if the consumer does not provide the correct amount of money for any tests ordered, the health facility professional can directly contact the consumer providing the sample. This is completely contrary to the method of the present invention, which protects the patient's anonymity from health facility professionals during receipt and handling of the test sample.

Thus, at a minimum, Fey neither teaches nor suggests "obtaining a test sample from the patient identified only by the Alias ID" as recited by claim 1. The Examiner has indicated that this feature is taught by Fey because Fey describes assigning a "unique identifier" to a consumer immediately prior to performing tests on a DNA sample provided by the consumer. *See* Office Action at page 3. However, as clearly set forth in Fey, the assignment of this unique identifier only occurs after the DNA sample has already been received and processed by the health facility:

> In the preferred embodiment, the DNA is safely stored in a secure environment at the central location of the health facility that assures stabilization for a specified number of years. When the consumer wishes to order a specific genetic test, the consumer pays a reasonable fee, the DNA sample on file is tested, and the information is entered into the database, along with any other screening tests, genetic or otherwise, that the consumer has completed at or through the facility.

Fey at paragraph [0070].

> Before the initial test, individuals are asked to sign consent forms.

Fey at paragraph [0071].

> At the point the consent information is entered, the computer automatically assigns a unique identifier to the client.

Fey at paragraph [0076]. Thus, in Fey, the unique identifier cannot possibly protect the consumer's anonymity during the phase in which the DNA sample is submitted by the consumer to the health facility, because this identifier is not assigned to the consumer until *after* the DNA sample has been received and processed. Instead, the purpose of assigning a unique identifier in Fey appears to be safeguarding test data pertaining to the user when such data is placed in Fey's medical database for ongoing storage, lest such data should fall into the hands of insurance carriers or employers. *See, e.g.,* Fey at paragraphs [0064] and [0076].

Moreover, it should be noted that the use of "unique identifiers" as described in Fey is fundamental to all record-keeping systems, due to the fact that "records"--be they representative of persons or whatever else--often share the same "name". The fact that Fey teaches the granting of a "unique identifier" to a client for record-keeping purposes does not in any way suggest that the client's anonymity is preserved during the submission and processing of the client's genetic sample.

In addition to not teaching or suggesting "obtaining a test sample from the patient identified only by the Alias ID" as recited by claim 1, Fey also does not teach or suggest "providing the test results to the patient using the Alias ID and Password" as recited by that claim. In Fey, the consumer is assigned a password to use on an Internet web site which stores the test results, which are downloaded directly from the medical database. *See* Fey at paragraph [0082]. Nowhere does Fey teach or suggest that the consumer must

use both this password and his/her unique client identifier when accessing this data over the Internet. In fact, it is not apparent from the teachings of Fey how the consumer would know what unique identifier has been assigned to his/her records when stored in the medical database.

Since Fey does not teach or suggest each of the features of independent claim 1, it cannot anticipate that claim. Dependent claims 4-7 are likewise not anticipated by Fey for the same reasons as independent claim 1 from which they depend and further in view of their own respective features. Accordingly, Applicants respectfully request that the rejection of claim 1 and 4-7 under 35 U.S.C. § 102(e) be reconsidered and withdrawn.

Independent claim 8 is directed to a method of obtaining test results anonymously that includes the steps of:

> obtaining an Alias ID and Password;
>
> providing a test sample for testing, wherein the test sample is identified by the Alias ID; and
>
> obtaining test results using the Alias ID and the Password.

For reasons discussed above with respect to independent claim 1, Fey does not teach or suggest "providing a test sample for testing, wherein the test sample is identified by the Alias ID" or "obtaining test results using the Alias ID and the Password" as recited in independent claim 8. Since Fey does not teach or suggest each of the limitations of independent claim 8, it cannot anticipate that claim. Dependent claims 11-14 are likewise not anticipated by Fey for the same reasons as independent claim 8 from which they depend and further in view of their own respective features. Accordingly, Applicants respectfully request that the rejection of claim 8 and 11-14 under 35 U.S.C. § 102(e) be reconsidered and withdrawn.

Independent claim 15 is directed to an anonymous testing kit that includes:

an Alias ID;

a Password; and

instructions on obtaining a test sample.

For reasons discussed above with respect to independent claim 1, Fey does not teach or suggest an anonymous testing kit that includes either an Alias ID or a Password as recited in independent claim 15. Since Fey does not teach or suggest each of the limitations of independent claim 15, it cannot anticipate that claim. Dependent claim 18 is likewise not anticipated by Fey for the same reasons as independent claim 15 from which it depends and further in view of its own respective features. Accordingly, Applicants respectfully request that the rejection of claims 15 and 18 under 35 U.S.C. § 102(e) be reconsidered and withdrawn.

Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 2, 3, 9, 10, 16 and 17 under 35 U.S.C. § 103(a) as being unpatentable over Fey. As set forth above, Fey does not teach or suggest each of the features of independent claims 1, 8 or 15. The Official Notice taken by the Examiner that "it is well-known that it would take [six or more] characters to come up with a unique client identifier" or that "it is well-known that it would take [four or more] characters to come up with a password to ensure access to the records"[1] does not provide

[1] Applicants also submit that the facts asserted to be well-known by the Examiner are not capable of "instant and unquestionable demonstration as being well-known" and thus are not appropriate subject matter for the taking of Official Notice. *See In re Zurko*, 258 F.3d 1379, 1385 (Fed. Cir. 2001)(holding that general conclusions concerning what is "basic knowledge" or "common sense" to one of ordinary skill in the art without specific factual findings and some concrete evidence in the record to support these findings will not support an obviousness rejection); *see also, generally,* MPEP § 2144.03.

the missing teachings or suggestions with respect to these independent claims 1, 8 or 15. Consequently, Fey does not render claims 2, 3, 9, 10, 16 and 17 unpatentable for at least the same reasons as the independent claims from which they depend and further in view of their own respective features. Accordingly, Applicants respectfully request that the rejection of claim 2, 3, 9, 10, 16 and 17 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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